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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): PA895

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 [37 CFR 1.8(a)] On March 26, 2007

Signature /Kimberly Melvin/

Type or printed Name Kimberly Melvin

Application Number	Filed
10/056,418	January 22, 2002

First Named Inventor: CAMPBELL, Todd

Art Unit	Examiner
3734	NGUYEN, Vi X.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor — /Alan M. Krubiner, Reg. No. 26,289/ Signature

☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96). — Alan M. Krubiner Typed or printed name

☒ attorney or agent of record. Registration Number 26,289. — 707.543.5021 Telephone number

☐ attorney or agent under 37 CFR 1.34. Registration number if acting under 37 1.34 _____ — March 26, 2007 Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/056,418	Confirmation No.:	8065
Applicant	:	CAMPBELL, Todd		
Filed	:	January 22, 2002		
TC/A.U.	:	3734		
Examiner	:	NGUYEN, Vi X.		
Docket No.	:	P895		
Customer No.	:	28390		
Title	:	STENT ASSEMBLY WITH THERAPEUTIC AGENT EXTERIOR BANDING		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Please consider these Remarks/Arguments for the above-identified application as set forth below.

REMARKS/ARGUMENTS

Review of the rejection of this Application is respectfully requested.

35 U.S.C. §103 Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations. *See* MPEP 2143. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to meet any of the three basic criteria.

Claims 34-36, 38, and 42 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 20010020181 to Layne (the *Layne* application) in view of U.S. Patent No. 6,096,070 to Ragheb, *et al.* (the *Ragheb* patent).

The *Layne* application discloses that a series of spaced apart ePTFE circumferential bands can be placed over the top of longitudinal strips and ringed stents. All of the components of the structure are then laminated to the inner ePTFE tube to capture the stent. By selecting the size and position of the ePTFE bands, it is possible to leave critical parts of the stent unencapsulated to facilitate flexibility and expansion. *See* Abstract. The ePTFE tube connected to the stent prevents cellular infiltration through the stent and restenosis. *See Layne* application, ¶ [0007]. The *Layne* application does not disclose use of a drug or therapeutic agent with the ePTFE circumferential bands, inner ePTFE tube, stent, or any component.

The *Ragheb* patent discloses a coated implantable medical device such as a coronary stent with at least one layer of a bioactive material posited on one surface, and at least one porous layer posited over the bioactive material layer. The porous layer is comprised of a polymer applied preferably by vapor or plasma deposition and provides a controlled release of the bioactive material. *See Ragheb* patent, Abstract. Degradation of an agent, a drug or a bioactive material applied to a vascular stent or other implantable medical device may be avoided by covering the agent, drug or bioactive material with a porous layer of a biocompatible polymer that is applied without the use of solvents, catalysts, heat or other chemicals or

techniques, which would otherwise be likely to degrade or damage the agent, drug or material. *See Ragheb* patent, column 3, lines 7-20.

The cited references when combined fail to teach or suggest all the claim limitations as required to establish a prima facie case of obviousness under 35 U.S.C. §103.

The Applicant respectfully asserts that the *Layne* application and the *Ragheb* patent, alone or in combination, fail to teach or suggest all the claim limitations. The cited references fail to disclose, teach, or suggest a stent assembly having a band circumferentially wrapped about a stent, comprising a polymer containing a therapeutic agent, and elastically gripping the stent, as recited in independent claims 34, 35, 36, and 42. *See* Applicant's Amendment filed November 13, 2006, pages 9-10.

The cited references fail to disclose a band comprising a polymer containing a therapeutic agent. The *Layne* application discloses a series of spaced apart ePTFE circumferential bands. *See Layne* application, Abstract. As noted by the Examiner, the *Layne* application is silent regarding the bands containing different therapeutic agents, but the *Layne* application is also silent as to the bands containing any therapeutic agent. The terms "drug" or "therapeutic agent" do not appear in the *Layne* application, which operates according to the principle that the ePTFE tube prevents cellular infiltration through the stent and restenosis. *See Layne* application, ¶ [0007]. Therefore, no drug is necessary in the *Layne* application. The *Ragheb* patent discloses a coated implantable medical device, but the coating is applied to the surface of the stent and not to a band. *See Ragheb* patent, Abstract. The *Ragheb* patent fails to disclose a band or any other component wrapped around the stent.

The cited references also fail to disclose a band elastically gripping the stent. The *Layne* application discloses a series of spaced apart ePTFE circumferential bands. *See Layne* application, Abstract. The strips and/or bands are configured in the desired pattern onto each of the structures, the structures are exposed to heat and pressure, thereby causing the ePTFE regions of the strips and/or bands to fuse or laminate to the tubular graft. *See Layne* application, ¶ [0021]. Therefore, the *Layne* application depends on fusing the ePTFE circumferential bands to the tubular graft to retain the ePTFE circumferential bands on the stent, rather than depending on elastically gripping the stent. In fact, the ePTFE material, which is the only band material disclosed in the *Layne* application, is inelastic and so incapable of gripping the stent. PTFE is stretched to several hundred percent of its original length to form ePTFE. *See* Layne application, ¶ [0006]. Radial expansion of a stent may stress and tear an ePTFE cover. *See* Layne

application, ¶ [0007]. Therefore, the band of the *Layne* application is not elastic and cannot elastically grip the stent. The *Ragheb* patent fails to disclose a band, let alone a band capable of elastically gripping the stent.

Claim 38 depends directly from independent claim 34 and so includes all the elements and limitations of its independent claim. The Applicant therefore respectfully submits that the dependent claim is allowable over the *Layne* application and the *Ragheb* patent for at least the same reasons as set forth above with respect to its independent claim.

There is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings as required establish a prima facie case of obviousness under 35 U.S.C. §103.

The Applicant respectfully asserts that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to combine the reference teachings. The *Layne* application is directed to the problem of providing an ePTFE tube on a stent and the *Ragheb* patent is directed to the problem of avoiding drug degradation in the coating process.

In addition, the *Layne* application has a completely different principle of operation than the *Ragheb* patent. The *Layne* application uses the ePTFE tube without any drug to prevent restenosis, while the *Ragheb* patent relies on bioactive materials. *See* the *Layne* application at ¶ [0007] *versus* the *Ragheb* patent at column 5, lines 48-51. The former operates without the use of drugs while the latter requires them. Therefore, there is no motivation to combine the *Layne* application and the *Ragheb* patent, and to do so is impermissible hindsight. *See* Applicant's Amendment filed November 13, 2006, page 9.

There is no reasonable expectation of success from combining the cited references as required establish a prima facie case of obviousness under 35 U.S.C. §103.

The Applicant respectfully asserts that there is no reasonable expectation of success from combining the cited references. The *Layne* application discloses a drug-free system for structurally supporting an ePTFE tube on a stent and the *Ragheb* patent discloses applying a porous coating over a drug on a stent. One of ordinary skill in the art would not expect success in combining the inventions of the *Layne* application and the *Ragheb* patent to produce a stent assembly having a band circumferentially wrapped about a stent, comprising a polymer containing a therapeutic agent, and elastically gripping the stent, as claimed by the Applicant. *See* Applicant's Amendment filed November 13, 2006, page 9.

Conclusion

Allowance of the claims in the subject case is requested in light of the above remarks.

Respectfully submitted,

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